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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,595	04/16/2004	Mark A. Hoffman	CRNI.114070	1203

46169 7590 06/06/2008

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EXAMINER	
SIMS, JASON M	

ART UNIT	PAPER NUMBER
1631	

MAIL DATE	DELIVERY MODE
06/06/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/826,595	HOFFMAN ET AL.	
	Examiner	Art Unit	
	JASON M. SIMS	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 February 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-14,16-23,25-31,33-40 and 42-51* is/are pending in the application.

4a) Of the above claim(s) *8,9,17,25,26,34,42,43 and 51* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,10-14,16,18-23,27-31,33,35-40 and 44-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/7/2008 has been entered.

Claims 8-9, 17, 25-26, 34, 42-43, and 51 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventive group, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 11/13/2006.

Claims 1-7, 10-14, 16, 18-23, 27-31, 33, 35-40, and 44-50 are the current claims hereby under examination.

Claim Rejections - 35 USC § 112-First Paragraph

Response to Arguments:

Applicant's arguments, filed 2/7/2008, with respect to the rejection of claims 11, 28, and 45 comprising new matter have been fully considered and are persuasive because of applicant's amendments. Therefore the rejection has been withdrawn.

Claim Rejections - 35 USC § 112-Second Paragraph

Response to Arguments:

Applicant's arguments, filed 2/7/2008, with respect to the rejection of claims under 35 USC 112 second paragraph have been fully considered and are persuasive because of applicant's amendments. Therefore the rejection has been withdrawn.

Claim Rejections - 35 USC § 103

Response to Arguments:

Applicant's arguments with respect to the rejection of claims under 35 USC 103 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-7, 10, 12-13, 16, 18-23, 27, 29-30, 33, 35-40, 44, 46-47, and 49-50 are rejected under 35 U.S.C. 102(e) as being anticipated over Hogan (US A/N 2002/0110823).

The claims are directed to a computer-implemented method for displaying a warning that a clinical agent received from a clinician should not be administered to a person, comprising the steps of:

receiving from a clinician clinical agent information, the clinical agent information including an identifier of a specific clinical agent;

determining if a gene is associated with the clinical agent by comparing the identifier of the clinical agent received from the clinician to a first data set containing agent-gene associations, and if a gene is associated with the clinical agent, obtaining a genetic test result value for the associated gene of the person;

comparing the genetic test result value to a second data set containing one or more polymorphism values associated with one or more polymorphism values with one or more atypical clinical events for the clinical agent; and

determining whether the genetic test result value correlates to one or more of the one or more polymorphism values contained in the second data set, and if so, displaying a warning to the clinician agent received from the clinician should not be administered.

Hogan teaches claims 1, 18 and 35 as follows: Hogan at the abstract discusses a method for tailoring a subject's surgical treatment to reflect genetic information. Hogan at paragraph [0005] discusses that the choice of anesthetic regimen, agent, and dose depends on the type of surgery or procedure. Therefore, it is implied that with planning a surgery a clinician will plan for the appropriate clinical agent, i.e. anesthesia drug, to be administered during the surgery, which reads on the first method step, receiving from a clinician clinical agent information, the clinical agent information including an identifier of a specific clinical agent. Hogan at paragraphs [0007] – [0009] discusses how certain genes are associated with particular anesthesic drugs. Hogan at Figs. 4 and 5

describes data sets that comprise genes, alleles and associations with particular clinical agents. Therefore, it is implied that when determining if a gene is associated with a particular clinical agent that it is through comparing the identifier of the clinical agent to a data set comprising agent-gene associations. Hogan teaches at paragraphs [0011] – [0013] discusses genomic screening of a subject prior or during a surgical procedure to obtain a genomic profile, which reads on the second step of determining if a gene is associated with the clinical agent by comparing the identifier of the clinical agent received from the clinician to a first data set containing agent-gene associations, and if a gene is associated with the clinical agent, obtaining a genetic test result value for the associated gene of the person. Hogan at paragraphs [0019] – [0022] discusses obtaining a genomic profile for a subject which screens the subject for one or more polymorphism values associated with one or more clinical events associated with one or more clinical agents. It is implied that the genomic profile result values are compared with a data set comprised of genes and alleles associated with clinical agents and events, such as in Figs. 4 and 5, which reads on the third method step comparing the genetic test result value to a second data set containing one or more polymorphism values associated with one or more polymorphism values with one or more atypical clinical events for the clinical agent. Hogan at paragraphs [0018] and [0019] discusses screening a patient to determine a risk for surgical complications associated with known genetic variations. Furthermore, Hogan at paragraph [0190] discusses that the risk assessment for the various treatment options are displayed to the clinician on a computer monitor, which reads on the final method step of determining whether the

genetic test result value correlates to one or more of the one or more polymorphism values contained in the second data set, and if so, displaying a warning to the clinician agent received from the clinician should not be administered. Moreover, Hogan at paragraphs [0189] – [0193] discusses the use of computers for performing the instant invention, all of which imply the use of computer programs and components for performing the instant method steps as in claims 18 and 35.

Hogan at paragraphs [0005], [0008], and [0138] discusses assessing the dosages associated with the clinical agents and risk assessments as in claims 2, 19, and 36.

Hogan at paragraphs [0186] and [0188] – [0193] discusses that the clinical agent and genetic information may be stored and communicated via various computerized applications, including electronic medical records including computers, which reads on claims 3, 10, 20, 27, 37, and 44.

Hogan at paragraph [0031] – [0033] discusses a problem is "how to alter treatment course of action in response to results," as in genomic screening results and the present invention unites "medicine with genetics" to solve the described problem and to individualize treatment options for each subject. The genomic screening and obtaining genomic profiles and Figs. 4 and 5 disclosed as examples of data sets comprising gene and allele associations with clinical agents implies a querying to determine if a gene is associated with a planned-to-be-administered clinical agent as in claims 4, 5, 21, 22, 38, and 39.

Hogan at paragraphs [0190] – [0191] teaches outputting information about the atypical clinical event associated with the polymorphism values such that a "clinical action" may be initiated as recited in claims 6, 13, 23, 20, 40, and 47.

Hogan at paragraph [0190] discusses that the risk assessment for the various treatment options are displayed to the clinician on a computer monitor, which reads on a warning that particular agents should not be administered as in claim 7.

Hogan at Fig. 4, discloses an example of a data set which includes information about risks associated with the atypical clinical events. Furthermore, at paragraphs [0115], [0129], [0136] – [0147], and [0186] teaches comparing genetic test result values for multiple genes to polymorphoism values associated with adverse reactions, i.e. risks associated with atypical clinical events, and that agent information may include dosage and other PK/PD parameters as in claims 12, 13, 16, 29, 30, 33, 46, and 50.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 11, 14, 28, 31, 45, and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hogan (US A/N 2002/0110823) as applied to claims 1, 18, and 35 above, and further in view of Hogan (US A/N 2002/0110823).

Hogan does not explicitly teach a method wherein the data sets of agent-gene associations may be updated as in claims 11, 28, and 45.

Hogan at Fig. 2 describes in the analysis step of comparing genomic profile values to gene-agent association data that research data may be included in a data set used for comparison.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to use data sets that may be updated. This is because it is a goal of the instant invention to tailor surgery treatments to subjects using genomic profiles and data, wherein it is implied that using the most updated genomic data available causes the instant invention to be used in its most opportunistic way. Therefore, it is implied that the gene-agent association data sets used are data sets that are updated as is also the nature of research, to update the current information existing in the field.

Hogan does not explicitly teach a method wherein the data sets are incorporated into a single data set as in claims 14, 31, and 48.

However, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to have used combined data sets as it can be a more efficient means for comparing data and easier for visually comparing or looking up information

such as gene-agent information. Furthermore, it is a common goal of researchers to consolidate the most updated information into single sources of data, wherein combining the most up to date information on gene-agent associations into a single source such as a single data set would be in line with research goals. Therefore, using a single source of data such as a single data set would be more efficient for determining risk assessments based on gene-agent associations.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason Sims, whose telephone number is (571)-272-7540.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Marjorie Moran can be reached via telephone (571)-272-0720.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

// Jason Sims //

/Michael Borin, Ph.D./

Primary Examiner, Art Unit 1631